



Figure 1. K-M probability of grade II-IV and III-IV acute GVHD

Objective: To determine efficacy of MMF administered q8h in combination with tacrolimus for acute GVHD prophylaxis in 39 children and young adult AlloSCT recipients.

Methods: GVHD prophylaxis consisted of tacrolimus 0.03–0.04 mg/kg/day IVCI on Day -1 or 1st day of conditioning (target range 10–20 ng/mL) and MMF 900 mg/m² (max 1.5 g/dose) or 15 mg/kg (age ≥ 18 y or weight ≥ 70 kg, max 1.5 g/dose) IV/PO q8h starting on Day +1. Patients were changed to PO tacrolimus (1:4 dose conversion IV:PO) as clinically appropriate post-AlloSCT. GVHD prophylaxis was continued until Day +180 followed by a taper in patients with non-malignant disorders. In patients with malignant disorders, MMF was discontinued on Day +30 or Day +60, followed by a slow tacrolimus taper starting on Day +60. Mycophenolic acid (MPA) trough concentrations were obtained if MMF-induced toxicity was suspected. aGVHD, chronic GVHD (cGVHD) and overall survival (OS) were determined by Kaplan-Meier (K-M) method.

Results: 39 patients (mean age 12 years [range 0.1–23.5 years]; 27 male vs 12 female) received myeloablative (n=20) and non-myeloablative (n=19) conditioning for malignant (n=28) and non-malignant disorders (n=11). Donor sources were: 6/6 MSD (n=12), 4/6–6/6 UCB (n=16), and 9/10 or 10/10 MUD (n=11). Sixteen/28 patients with malignant disease were poor risk. Median time to myeloid and platelet engraftment was 16 and 32 days, respectively. Probability of grade II-IV aGVHD and grade III-IV aGVHD was 16.6% (CI₉₅: 1.8–44.7) and 2.9% (CI₉₅: 0–60.6), respectively (n=37 evaluable patients). [Figure 1] Only one patient experienced grade III (liver +gut) aGVHD, with no patients developing grade IV aGVHD. Probability of limited + extensive cGVHD (n=34 evaluable patients) was 23.6% (CI₉₅: 8.0–50.5).

Nine patients died at a median 198 days post-SCT (range 109–549). Causes of death included chronic GVHD (n=2), acute GVHD (n=1), TMA (n=1), viral or fungal infection (n=2), relapse (n=2), and EBV PTLN (n=1). K-M probability of 1 year overall survival was 72.5% (CI₉₅: 53.3–84.9).

Conclusion: Tacrolimus in combination with MMF given q8h as described above are highly effective for aGVHD prophylaxis in this heterogeneous group of pediatric and young adult AlloSCT recipients. The incidence of grade II-IV aGVHD in the current study appears to be substantially lower than reported in our previous trial with MMF dosed at 900 mg/m² q6h in a similar group of pediatric and adolescent AlloSCT recipients (16.6% vs 54.4%). [Bhatia/Cairo et al. BBMT 2010;16(3):333–343]

Results of the American Society for Blood and Marrow Transplantation Pharmacy Special Interest Group Practice Survey – Understanding Today to Meet the Needs of Tomorrow

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The National Marrow Donor Program (NMDP) has estimated that the number of hematopoietic stem cell transplants (HSCTs) performed will double by 2015 as compared to 2010. The NMDP also projects a shortage of physicians, physician assistants, nurses, nurse practitioners, and pharmacists. In response to this anticipated shortage, the American Society for Blood and Marrow Transplantation (ASBMT) Pharmacy Special Interest Group (SIG) was created in 2012. The ASBMT Pharmacy SIG recognized the need to engage non-physician providers in the care of patients and supplement the training of such practitioners. The ASBMT Pharmacy SIG has prioritized the education of these practitioners and has successfully developed and implemented the Fundamentals of HSCT course to address this issue.

Another priority of the ASBMT Pharmacy SIG was to determine the value of HSCT pharmacists in clinical practice. Thus, a survey was conducted in January 2014 to collect baseline data of the current ASBMT Pharmacy SIG make-up and practice patterns. The survey was distributed to approximately 250 participants and 56 surveys were returned. Of the 56 responders, most practitioners worked in academic medical centers (91%) with the majority of centers performing less than 300 HSCTs per year (85%). Most institutions had 3 or fewer pharmacists dedicated to HSCT services (68%). The highest level of training and certification for the majority of pharmacists practicing in HSCT was a post-graduate year 2 oncology pharmacy practice residency (64%) and a board certification in oncology pharmacy (61%), respectively. Though the majority of practitioners spent anywhere from 50–100% of their time dedicated to clinical activities, only 25% of practitioners had an established collaborative practice protocol in place. Furthermore, most HSCT pharmacists spent 20% or less of their time devoted to teaching, administrative, or research activities. Many practitioners were involved with pharmacy organizations and spent time outside of their clinical duties to work on publications and professional development.

The results of this survey provide a snapshot of the current HSCT pharmacy climate and may be used as a tool to educate healthcare practitioners on roles and responsibilities of HSCT pharmacists. These results may also serve as foundation for the development of HSCT pharmacist competencies in the future and a framework for

future analyses, such as determination of value of services, which in turn could support the justification of HSCT pharmacy services.

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Withdrawn

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Intravenous Pentamidine for *Pneumocystis Carinii*/Jiroveci Pneumonia (PCP) Prophylaxis

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Background: Sulfamethoxazole/trimethoprim (SMX/TMP) is the current gold standard for PCP prophylaxis in hematopoietic stem cell transplant (HSCT) patients. There are several second line options for prophylaxis but many, including intravenous (IV) pentamidine, have not been proven to be as effective or as safe as SMX/TMP in the pediatric HSCT population. There is increasing use of IV pentamidine in the pediatric HSCT population, as it is easily given once monthly, with no issues regarding compliance or vomiting. However, there are limited published data to support safety and efficacy of this approach. This study was aimed to determine the safety and efficacy of IV pentamidine in preventing PCP infection in our pediatric HSCT patients.

Methods: A retrospective chart review was conducted with IRB approval to evaluate all HSCT patients at Cincinnati Children's Hospital Medical Center (CCHMC) that received at least one dose of IV pentamidine from January 2010 to July 2013. The primary outcome, pentamidine efficacy, was evaluated through lack of breakthrough PCP infection. The secondary outcome, pentamidine safety, was evaluated by adverse events leading to pentamidine discontinuation.

Results: Total of 285 HSCT patients received at least one dose of IV pentamidine and were included in the final analyses. Median age of patients was 5 years (range: 0.2 to 32 years). Patients were on pentamidine prophylaxis for a median of 5 months (range 1–44 months). Only 1 patient developed breakthrough PCP infection while receiving IV pentamidine prophylaxis (0.35%). Two patients were diagnosed with toxoplasmosis while receiving pentamidine prophylaxis (0.7%). Twenty patients (7%) experienced an adverse event leading to discontinuation of pentamidine, with tachycardia being the most common adverse event leading to discontinuation of pentamidine. The rate of adverse effects seen with pentamidine is comparable to that seen in patients receiving SMX/TMP prophylaxis which is associated with adverse effects ranging from 3.1–59%.

Conclusion: In a three year time span only 1 patient (0.35%) receiving IV pentamidine prophylaxis had a breakthrough PCP infection. Although SMX/TMP is considered first line for PCP prophylaxis, based on the results of this study, IV pentamidine should be considered a safe and effective alternative in pediatric HSCT patients. Of note, pentamidine does not provide toxoplasmosis suppression, a consideration for children considered at high risk of reactivation.

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Hepatitis B Immune Globulin Prophylaxis of Viral Reactivation during Stem Cell Transplant

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Background: Stem cell transplant patients who are hepatitis B negative at the time of transplant and receive stem cells from a hepatitis positive donor have a higher risk of liver related post-transplant complications and hepatitis viral positivity. The use of lamivudine has been documented in the literature as chemoprophylaxis for preventing viral reactivation in positive patients and also surface antigen negative patients receiving stem cell product from hepatitis positive donors. The expected duration of chemoprophylaxis with lamivudine therapy is multiple months following stem cell transplant. This is a case series of using a two dose course of hepatitis B immune globulin, without lamivudine, for the prevention of viral seroconversion in stem cell transplant recipients.

Methods: This is a single center retrospective chart review of three pediatric stem cell transplant patients who were prescribed hepatitis B immune globulin for prophylaxis of seroconversion of hepatitis B. Hepatitis B immune globulin 0.06mL per kilogram was administered as two doses, on day -1 or day 0, and repeated four weeks later. All patients received allogeneic transplantation from matched related donors, found to be positive for hepatitis B prior to stem cell harvest. Diagnoses for stem cell transplant of the patients were acute lymphoblastic leukemia, congenital myelofibrosis and cartilage hair hypoplasia. Patient age ranged from 1 to 17 years.

Results: At median of 20 months follow up (range 12–32 months), no patients were reported to have a positive hepatitis B DNA after stem cell transplant. No cases of veno-occlusive disease of the liver were observed. This small case series may present an alternative, simpler prophylaxis regimen that is effective at preventing hepatitis viral transmission during stem cell transplant.

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Adverse Events during Peripheral Blood Hematopoietic Stem Cell Mobilization in Light Chain Amyloidosis Patients

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Background: High-dose chemotherapy with autologous hematopoietic stem cell transplantation (auto-HCT) can be an effective treatment for systemic light chain amyloidosis (AL). However, significant morbidity may occur in AL patients undergoing peripheral blood stem cell (PBSC) mobilization, especially if they have cardiac or renal involvement. Reported complications include fluid overload, cardiac arrhythmias, bleeding events, and infections.

Methods: We identified 101 patients with AL who underwent PBSC mobilization and collection with filgrastim at a dose of 10 mcg/kg/day between 2006 and 2013. Fifteen patients (15%) also received plerixafor at a dose of 0.16–0.24 mg/kg/day after at least 4 days of filgrastim. The primary